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MANUFACTURERS' REACTIONS IN RESPONSE TO THE NEW REQUIREMENT FOR COST-EFFECTIVENESS IN FRANCE

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OBJECTIVES: In France, decree n°2012-1116 passed on 2 October 2012 made it mandatory for manufacturers of medicines to submit a cost-effectiveness model to the Economic and Public Health Assessment Committee (CEESP) when requesting an Improvement of Medical Benefit (ASMR) of I-III in their reimbursement submission to the Transparency Committee (CT). Our objective was to gauge the impact of this decree on the ASMR levels requested by manufacturers. **METHODS:** We investigated ASMR I-III levels requested before and after the adoption of the decree. All CT meeting minutes published by the French National Authority for Health (HAS) between January 2012 and March 2015 were reviewed. Four time periods were evaluated: 1. 04/01/2015 – 03/10/2012; 2. 04/10/2012 – 03/10/2013 (the day it took effect); 3. 04/10/2013 – 01/10/2014; 4. 02/10/2014 – 18/03/2015. Additionally we looked at initial submissions for new medicines, assuming these were more susceptible to be influenced by the new decree. If manufacturers increased the number of requests made for ASMR I-III in period two and then subsequently decreased them, this would suggest they were trying to avoid submitting cost-effectiveness models. **RESULTS:** Over the study period there were 231 ASMR requests of which 83 (35.9%) were for an ASMR I-III and 135 (58.4%) for an ASMR IV or V. The proportion of ASMR I-III requests for periods one, two, three and four were 19 (40.4%), 16 (27.1%), 29 (35.4%) and 19 (44.2%) respectively. Of the 83 ASMR I-III requests 47 were initial submissions: 12 (35.3%) period one; six (18.2%) period two; 17 (35.4%) period three; 12 (52.2%) period four. **CONCLUSIONS:** Against the baseline period, total requests for an ASMR I-III fell from 40.4% to 27.1% of all requested ASMRs, only to increase in each of the subsequent two periods. A similar pattern holds for initial submissions. These results suggest manufacturers didn't change their behaviour to avoid submitting cost-effectiveness models.

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HEALTH TECHNOLOGY ASSESSMENT TOOLS FOR TECHNOLOGIES INCORPORATION INTO PUBLIC HEALTH SYSTEM

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OBJECTIVES: The health technology assessment (HTA) is used, among other functions, in order to support decision-making on the incorporation of new technologies in public health systems. Generally, those decisions are based on criteria such as efficacy, effectiveness, safety and cost-effectiveness and, besides that the health system context as a whole has also a great influence on reimbursement/investment on health technologies and such informations are not always explicit or well weighted in a systematic way. Thus, this work aims to raise and compare systematic HTA tools and its criteria used during the decision-making process on new technologies incorporations in different health systems. **METHODS:** A review was conducted, then studies describing systematic methods of HTA on reimbursement/investment decision-making in public health system were selected and finally a descriptive analysis was performed. **RESULTS:** As HTA systematic tools there were found multicriteria decision analysis (MCDA), assessment scoring system and public health benefit of medicines (PHB), among others. In addition to efficacy, effectiveness, safety and cost-effectiveness criteria, some evaluations had also considered other elements, namely: epidemiology, disease burden, quality-adjusted life year (Qaly), presence of therapeutic alternative, societal value, patient impact, quality of the evidence, innovativeness, impacts on equity, ethical consequences, convenience, feasibility and acceptability. A major barrier found in multicriteria evaluation was the lack of reliable data for all criteria. **CONCLUSIONS:** This study has raised HTA experiences in a variety of public systems proving that HTA normally takes multicriteria into account. However not all of them are considered multicriteria analysis (MCA) because this technique generally supply an explicit relative weighting system for the different criteria and not all HTA proceed in this manner. Generally, it was noted that the use of multicriteria can contribute to objectiveness, transparency and accountability of the process, thus enhancing legitimacy of the political decisions.

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A RETROSPECTIVE ANALYSIS OF TIME TO MARKET ACCESS AND THE REGIONAL IMPACT OF SPANISH 'PLACE IN THERAPY' REPORTS

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OBJECTIVES: In December 2012, the Spanish Government approved publication of the Spanish 'Place in Therapy' reports (IPTs [Informes de posicionamiento terapéutico]) which are used to inform pricing and reimbursement decisions with the Ministry of Health. These reports were implemented to create a single national assessment and thereby negate the need for regional decision making, and ensuring equal access to therapies throughout Spain. A further aim of IPTs was to ensure fast access, with the Spanish Government committing to their publication within 3 months of European Medicines Agency (EMA) approval. This analysis aimed to determine whether IPTs have successfully met their objectives. Can manufacturers expect IPT publication within 3 months post-EMA approval and have they successfully prevented regional assessments, thereby ensuring equal access throughout Spain? **METHODS:** A retrospective analysis of IPTs from their implementation in 2012 to present was carried out by extracting information from the Spanish Medicines Agency, from the EMA and from the regional health technology assessment boards. **RESULTS:** To June 2015, 38 drugs have been assessed via an IPT, two of which were assessed for more than one indication. The average time from EMA authorisation to IPT publication is 25 months. This is reduced to 14 months when only drugs marketed after December 2012 are considered. Seventy percent of the drugs evaluated via the IPT procedure have also been evaluated via a regional assessment, of which, 68% were evaluated at a regional level prior to the publication of the national assessment. **CONCLUSIONS:** This report indicates that manufacturers can expect delays in the publication of national IPTs. Furthermore, manufacturers can still expect their products to be evaluated at a regional level, regardless of undergoing the national procedure. Regional decisions may still be taking place due to the prolonged time taken for the publication of these national reports.

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TRENDS IN NON-SUBMISSIONS IN THE UK

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OBJECTIVES: Manufacturers of products selected for NICE appraisal are able to choose whether or not to present submissions. Choosing not to submit results in termination of the appraisal, with words to this effect recorded on the NICE website. As the reimbursement landscape in Scotland can differ to that in England and Wales, a comparison was made between the SMC submission status and the non-submission status recorded by NICE. **METHODS:** This study reviewed previous NICE appraisals and examined trends in technologies and disease areas where a decision to not submit to NICE was taken. Single technology appraisals (STAs) listed as "Terminated appraisal – non submission" on the NICE website were identified, with terminated appraisals categorised by year and disease area. Products that did not submit were entered into the SMC website to see whether a submission was made to the SMC. Trends in non-submissions were identified. **RESULTS:** A total of 189 NICE STAs were identified. Of these, twenty submissions were recorded as non-submissions. Two of these submissions were later replaced by updated technology appraisals (TA147 and TA150). The frequency of non-submission varied by year, with five non-submissions recorded in 2013. Over half of these terminated submissions were in oncology. A comparison was made against submissions to the SMC. Of the twenty non-submissions to NICE only six reviews in matching indications were identified for the SMC. Of these four submissions were identified as full submissions. **CONCLUSIONS:** The decision to not submit to NICE was taken in 10% of STAs identified. Of those matched on the SMC website, four full submissions were received by the SMC. Further analysis regarding the implications on reimbursement and patient access differences across the UK should be undertaken.

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INNOVATION RANKING IN FRANCE AND ITALY: DIFFERENCES AND THEIR IMPACT ON PRICING AND REIMBURSEMENT PROCESSES

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OBJECTIVES: To investigate differences between therapeutic innovative criteria currently used in France and Italy and their implications for pricing and reimbursement. The French (Haute Autorité de Santé, HAS) and Italian (Agenzia Italiana del Farmaco, AIFA) national authorities both evaluate therapeutic innovation of new medicines as part of their drug approval process. This comparative analysis examines criteria used to assess innovation in France (Service Médical Rendu [SMR]; Amélioration du Service Médical Rendu [ASMR]) and Italy. **METHODS:** Peer-reviewed literature including French and Italian reports and health technology assessment (HTA) websites were searched for publically-available records of new drugs evaluated for therapeutic innovation in France and Italy since 2010. Eighteen drugs on the Italian innovative drug list were compared against French SMR and ASMR rankings. **RESULTS:** The findings of this study show similarities between the decision-making processes in each country. However, differences exist in the algorithms applied to evaluate therapeutic innovation, leading to different outcomes in each country. For example, in 2012 ipilimumab was classified as an 'H' class drug (only fully reimbursed in hospitals) and ranked 'important' for innovation in Italy. On the other hand, in France, ipilimumab received an 'important' SMR score (i.e. 65% level of reimbursement) but only an ASMR score 'IV' for innovation (minor improvement in actual benefit in terms of therapeutic strategy). **CONCLUSIONS:** France and Italy currently have complex systems for determining therapeutic innovation to set clinical value and reimbursement rates. Inconsistencies between the countries may lead to disparities in access and in pricing and reimbursement of innovative medicines. Further clarification of the terminology used in each set of criteria is required in both countries. France may benefit from the implementation of a simplified new therapeutic index (e.g. Relative Therapeutic Index, new criteria proposed in 2012).

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ORGANIZATIONAL MODELS OF HOSPITAL BASED HTA: EMPIRICAL EVIDENCE FROM ADHOPHTA EUROPEAN PROJECT

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OBJECTIVES: Hospital Based Health Technology Assessment (HB-HTA) became increasingly relevant because of its role in ensuring the introduction of evidence-based technologies and eventually in enhancing better outcomes for end-users. The organizational arrangements performed to run such activities are different and depend on several factors, even if some common points may be considered as minimal basis. The aim of this study is to identify and critically appraise existing different organizational models for HB-HTA. **METHODS:** Data used in this study was gathered within European Project AdHopHTA, granted under the 7th Framework Research Programme, which is aimed at strengthening the use and impact of HTA in hospital settings. A semi-structured interview was developed from the adaptation of the European Foundation for Quality Management Model, in order to inquire several aspects characterizing the organizational model. Finally, 7 HB-HTA units were involved in the study. **RESULTS:** Our results show that the organizational models depend on a number of contingent variables. Specifically, the combination of the level of formalization/specialization and the degree of integration with the